Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Standing agenda item: review of developments in the field of science and technology related to the Convention

The United States of America Government oversight of life sciences dual use research of concern

Submitted by the United States of America

I. Background

1. Despite its value and benefits, certain types of life sciences research, conducted for important and legitimate purposes, can have the potential to generate knowledge, information, products, or technologies that, in the wrong hands, could be misapplied for harmful purposes. Such research is characterized as "dual use" research. The international community has recognized the need for balanced, responsible policies to manage dual use risks without impeding the societal benefits derived from such research.

2. As a result, several entities have fostered what has become an international dialogue regarding dual use oversight of the life sciences, including the World Health Organization (WHO)[1], Royal Netherlands Academy of Arts and Sciences[2], German Ethics Council[3], and the U.S.A. Government[4], including through its National Science Advisory Board for

[1] Meeting on "Dual Use Research of Concern: Current Issues and Innovative Solutions," World Health Organization, 26-28 February 2013, Geneva, Switzerland. Report available at http://www.who.int/csr/durc/durc_feb2013_full_mtg_report.pdf?ua=1.

[2] *Improving Biosecurity: Assessment of dual-use research*, Royal Netherlands Academy of Arts and Sciences, December 2013, ISBN 978-90-6984-678-1. Report available at http://www.knaw.nl/en/news/publications/improving-biosecurity-1.

[3] *Opinion: Biosecurity – freedom and responsibility of research*, German Ethics Council 7 May 2014. Summary and recommendations available at http://www.ethikrat.org/welcome?set_language=en.

[4] http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-of-concern/international-engagement.

Biosecurity. A dynamic dialogue continues within the Biological Weapons Convention (BWC) itself, as reflected in presentations[5], side events[6], and statements by several States Parties[7].

3. In 2012, the U.S.A. Government issued the Policy for Oversight of Life Sciences Dual Use Research of Concern[8], requiring U.S. federal departments and agencies that fund life sciences research to identify and manage the risks associated with dual use research of concern (DURC). DURC is a small subset of dual use research, defined by the U.S.A. Government as "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." The 2012 U.S.A. Government DURC policy seeks to mitigate risks created by DURC by establishing regular federal review of U.S.A. Government-funded or -conducted research involving specific high-consequence pathogens and toxins. The aim of this federal oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies generated by such research.

II. A New U.S.A. Government Policy for Institutional Oversight of Life Sciences DURC

4. In recognition of the pivotal role of research institutions and their scientists in identifying and managing DURC, the U.S.A. Government will release a second policy that expands DURC oversight to research institutions receiving U.S. federal funding. The forthcoming Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern[9] (DURC institutional policy) will articulate the practices and procedures required to ensure that DURC is identified at the institutional level and that risk mitigation measures are implemented as necessary. The institutional DURC policy will complement the 2012 DURC policy by establishing institutional review processes and oversight requirements for institutions receiving federal funding for life sciences research. In developing the institutional DURC policy the U.S.A. Government received input from the research community, academia, scientific associations, and other members of the American public to develop a policy that promotes open sharing of research results while seeking to minimize their potential misuse. Together, the two U.S.A. Government DURC oversight policies

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[5] Plenary presentations to the 2013 BWC Meeting of States Parties (MSP) by the Netherlands (*Biosecurity in the Netherlands*) and to the 2013 BWC Meeting of Experts (MXP) by WHO (*WHO 2013 Informal Consultation on Dual-Use Research of Concern*).

[6] Side events at the 2013 MSP by the Royal Netherlands Academy of Arts & Sciences (*Improving Biosecurity - Assessment of Dual Use Research*); at the 2013 MXP by Indonesian Academy of Sciences and Royal Netherlands Academy of Arts and Sciences (*Dealing with Dual Use Research of Concern*); at the 2012 MSP by Canada (*Awareness of the Dual-Use Challenges into Biosafety and Biosecurity Training and Education for Life Scientists*); and at the 2012 MXP by the Netherlands and the U.S. (*Dual Use Research of Concern: The H5N1 Controversy and its Implications for Science Governance*).

[7] Opening statements to the 2013 MXP by the Russian Federation (page 2), Malaysia (page 2), India (page 1) and Switzerland (page 5); S&T plenary statement to the 2013 MXP by Iran on behalf of the Non-Aligned Movement and Other States Parties; National Implementation plenary statement to the 2013 MXP by Switzerland; and opening statements to the 2012 MSP by Pakistan (page 3), India (page 3), U.S. (page 2), and Chile (page 1).

[8] http://www.phe.gov/s3/dualuse/documents/us-policy-durc-032812.pdf.

[9] http://www.phe.gov/s3/dualuse.

work to engage life sciences research institutions and federal funding agencies in a shared responsibility to address the risk that knowledge, information, products, or technologies generated from life sciences research could be used for harm. In addition, the two U.S.A. Government DURC oversight policies together emphasize a culture of responsibility by reminding all involved parties of the shared interest in upholding the integrity of science and in preventing its misuse.

5. Research that is categorized as DURC is often vitally important to science, public health and agriculture, and its findings often contribute meaningfully to the broader base of knowledge that advances scientific and public health objectives. Therefore, it is important to emphasize that a determination of research as being in the category of DURC does not suggest that the research should not be conducted, nor is it the intention of the institutional DURC policy to discourage its pursuit. Rather, a DURC determination indicates a need for greater oversight, and for a collaborative and informed assessment of the potential benefits and risks of the research. In recognition of this, both U.S.A. Government DURC policies note that oversight of DURC, including implementation of risk mitigation measures, should minimize, to the extent possible, adverse impact on legitimate research; should be commensurate with the risk; should include flexible approaches that leverage existing review processes; and should endeavor to preserve and foster the benefits of research.